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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,121	01/13/2000	Ralf Reiner Schumann	103888-307-NP	9305

7590 06/28/2004

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/484,121	<b>Applicant(s)</b> SCHUMANN ET AL.	
	<b>Examiner</b> Chih-Min Kam	<b>Art Unit</b> 1653	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 03 June 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☒ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☒ Newly proposed or amended claim(s) 34-36 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 34-41.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☒ Other: Interview summary on 3/2/04

  
 CHRISTOPHER S. F. LOW  
 SUPERVISORY PATENT EXAMINER  
 TECHNOLOGY CENTER 1600

Continuation of 2. NOTE: The amendment to the claims raises new matters regarding the serum concentration of lipopolysaccharide binding protein is from 15 to 275 ug/ml (climas 38-40). In the amendment of June 3, 2004, claim 34 and 38-40 have been amended, and claims 37 and 41 are withdrawn from consideration. Applicants' response has been fully considered, however, claims 38-40 are rejected under 35 U.S.C.112, first paragraph, and also objection to new matter added to specification.

If applicants' amendment to claims 34-38 were entered, it would have the following response:

1. Claims 38-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 38-40 are directed to a process for detoxifying bacterial lipopolysaccharide in a patient with septicemia, comprising administering an effective amount of lipopolysaccharide binding protein (LBP) to elevate the serum concentration of LBP to a sufficiently high level to suppress lipopolysaccharide induced release of cytokine, wherein the serum concentration of LBP is from 15 to 275 ug/mL. The specification only shows the LBP in the mouse is up to 10 ug/mL when 100 ug of mLBP was added (see Fig. 4), it does not indicate the serum concentration of LBP is in the range of 15 to 275 ug/mL, which is obtained from a clinical study of human patients in a post filing publication of Inventors (Blood, 98, 3800-3808, 2001). Because of the lack of description of the serum concentration of LBP is from 15 to 275 ug/mL in the method of detoxifying bacterial lipopolysaccharide as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

2. The amendments filed June 3, 2004 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The specification does not indicate the serum concentration of LBP is from 15 to 275 ug/mL in the method of for detoxifying bacterial lipopolysaccharide (see page 3, lines 16-18: Fig. 4), however, the amended claims 38-40 recite the new matters. Applicant is required to cancel the new matter in the reply to this Office Action.

Continuation of 3. Applicant's reply has overcome the following rejection(s): If entered, the rejection of claims 34-36 under 35 USC 112, first and second paragraphs.

Continuation of 5. does NOT place the application in condition for allowance because: objection to new matter added to the specification, and new claims 38-40 are rejected under 35 U.S.C. 112, first paragraph.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

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June 24, 2004